Remarks/Arguments

Reconsideration of this Application and entry of this Amendment are respectfully requested. Claims 1-9 and 23-25 are pending in this application. Claims 10-22 were previously withdrawn without prejudice as the result of an earlier restriction requirement.

Applicant acknowledges that the 35 USC §102 rejection over US Patent 6,821,264 and DE 4028622 was withdrawn as a result of Applicant's amended claims filed on September 22, 2005.

Rejections under 35 U.S.C. §102(a)

Claims 1-4, 7-8, and 24-25 have been rejected under 35 U.S.C. §102(a) as being anticipated by RU 2176511 C1 (the '511 patent).

Claim 1 has been amended to advance the present claims to allowance without prejudice to re-introducing the original claims in continuing applications. Support for the amendments to claim 1 can be found throughout the specification. See for example paragraphs 0062 through 0068. Additional specific references to the specification to support claim amendments and as a basis for rejection traversal will be made *supra*. No new matter was introduced as a result of the amendments to claims 1. Dependent claims 2, 5 and 8 have been cancelled. Applicant has reproduced amended claim 1 below for ease of discussion:

1. A therapeutic composition for treating skin diseases comprising:

substantially pure powdered Spongilla sp. ~~a Porifera-derived product~~ made in accordance with Good Manufacturing Practices (GMP) ~~wherein said Porifera-derived product comprises a substantially pure powder of a Porifera species~~ and at least one pharmaceutically acceptable excipient wherein said therapeutic composition is not an extract of said substantially pure powdered Spongilla sp.

The Examiner has stated that the '511 patent "disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient

(abstract)." Applicant respectfully disagrees that the '511 patent discloses the presently claimed invention.

The '511 patent discloses "[t]he applicant found that a water-alcohol freshwater sponge extract is capable of prevented [sic] the clogging of the orifices and ducts of sebaceous glands..." (page 3 of the translation provided with the Office Action). The '511 patent discloses that "[i]n order to obtain a water-alcohol freshwater sponge extract, the ground sponge is extracted with 40-70% ethyl alcohol and the suspended particles are removed." (Emphasis added) As specifically disclosed in the patent specification, the '511 patent is limited to an extract because the composition is intended for the prevention of clogging of the orifices and ducts and that the extract is a liquid, free of particulates.

The presently claimed therapeutic composition comprises a substantially pure powdered Spongilla sp., wherein the powder is made from the entire Spongilla organism which has been separated from environmental debris, washed, dried, ground, sieved and sized (paragraph 0085). For example, at paragraph 0062 at line 14 of the originally filed application that Applicant states:

> "Furthermore, refined organic residue, such as, but not limited to, skeletal spicules mechanically separate epidermis surface layers reduces the keratinocytes cohesion thereby increasing stratum corneum sloughing and sebum plug and loose keratinocyte removal, which opens pores and prevents future occlusion and consequent formation of comedones " (Emphasis added)

See also at paragraph 0068:

> Compositions made in accordance with the teachings of the present invention have been analyzed extensively. The desiccated and granulated raw material of the present invention is an odorless, grayish-red non-hygroscopic powder. The powder is partially soluble in water and forms a greenish-red colored solution when mixed in a ratio of 1 part to 3; approximately 50 to 60% percent remains insoluble and comprises the

organic fraction providing compositions of the present invention with mechanical-abrasive properties." (Emphasis added)

Therefore, as can be seen form the preceding cited section for the as filed application, the present invention is not a mere alcohol-aqueous extract of fresh water sponges as disclosed in the '511 patent, but rather is a composition that comprises the whole organism that has been substantially purified as described at paragraph 0087 of the originally filed application.

In order for a reference to anticipate a claim under 35 U.S.C. §102(a), each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. The '511 patent does not disclose, either expressly or inherently, a substantially pure powdered Spongilla sp. The '511 patent does not disclose a powder of a Spongilla sp. Further, the '511 patent does not disclose a non-extracted Spongilla composition. In fact at page 3 of the USPTO official translation, the inventor of the '511 patent specifically states at page 3 "[t]his object was achieved as a result of using a water-alcohol extract of a freshwater sponge of the family Spongillidae;" (Emphasis added) At the last paragraph on page 3 the inventor of the '511 patent continues: "[t]he essence of the applicant's proposal is as follows. For prophylaxis of acne disease, and also for treatment thereof the initial stages, the skin of people predisposed to acne is treated with an agent containing a water-alcohol extract of a freshwater sponge..." (Emphasis added) The applicant of the '511 patent does not disclose or fairly suggest a therapeutic Spongilla sp. composition comprising substantially pure powdered Spongilla sp. in combination with a pharmaceutically acceptable excipient used for the treatment of skin diseases as disclosed and claimed in the present invention.

Therefore, because each and every limitation of independent claim 1 is not found, either expressly or inherently in the '511 patent, specifically "a substantially pure powdered Spongilla sp. made in accordance with Good Manufacturing Practices (GMP) combined with at least one pharmaceutically acceptable excipient wherein said therapeutic composition is not an extract of said substantially pure powdered Spongilla" claim 1 not anticipated by the '511 patent. Furthermore, since independent claim 1 is

not anticipated by the '511 patent, presently pending dependent claims 3, 4, 7 and 24-25 are also not anticipated. Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(a) of claims 1, 3, 4, 7 and 24-25 and pass these claims to allowance.

Rejections under 35 U.S.C. §103(a)

Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over 2176511 C1 (the '511 patent) in view of U.S. Patent No. 3,896,238 (the '238 patent).

Applicant has cancelled claim 9, therefore, the Applicant respectfully asserts that this rejection is now moot and respectfully requests its withdrawal.

Rejections under 35 U.S.C. §101

Claims 1-9 and 23-25 have been rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Applicant respectfully disagrees. Claims 2, 5, 8 and 9 have been cancelled as a result of this amendment. Claim 1 has been amended as disclosed above.

Section 101 of the Patent Act establishes categories of patentable subject matter as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

A true "product of nature" may not be patented because it does not constitute a machine, composition or matter or manufacture. See *P.E. Sharpless Co. v. Crawford*, 287 F.655 (2d Cir. 1923). Any significant alteration of the product from its natural state would seem to make the product a "manufacture" and therefore not a "product of nature." See *In re Kratz*, 592 F.2d 1169, 1173-1174, 201 USPQ 71, 75-76 (CCPA 1979). Furthermore, in order to be considered a true "product of nature," the claimed invention must exist in its claimed form in nature. See *Funk Bros. Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948).

The presently claimed invention provides a "whole substantially pure powdered Spongilla sp. made in accordance with Good Manufacturing Practices (GMP) combined and at least one pharmaceutically acceptable excipient wherein said therapeutic composition is not an extract of said substantially pure powdered Spongilla sp." The substantially pure powdered Spongilla sp. is made from the entire Spongilla sp. organism which has been separated from environmental debris, washed, dried, ground, sieved and sized (paragraph 0085) under controlled GMP manufacturing conditions.

Applicant acknowledges the Examiner's position that patentable subject matter includes "anything under the sun made by man" (*Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980)). The claimed invention is "made by man" as the substantially pure powdered Spongilla sp is made from the entire Spongilla sp. organism which has been separated from environmental debris, washed, dried, ground, sieved and sized under controlled GMP manufacturing conditions. The substantially pure powder which has been separated from environmental debris, washed, dried, ground, sieved and sized does not occur in nature and requires the disclosed manufacturing steps to produce the claimed invention.

Therefore, Applicants respectfully assert that the claimed invention comprises patentable subject matter and respectfully request that the rejection of claims 1-9 and 23-25 under 35 U.S.C. §101 be withdrawn.

Conclusion

Claims 1-25 are pending in the instant application; claims 10-22 have been withdrawn, claims 2, 5, 8 and 9 have been canceled and new claim 26 added. For the foregoing reasons, Applicant believes pending claims 1, 3, 4, 6, 7, and 23-26 are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at 949-253-0900.

Applicant has filed a request for extension of time with this response in order to bring the period for reply to April 6, 2006. The Commissioner is authorized to charge any fee which may be required in connection with this action or credit any overpayment to deposit account No. 50-3207.

Dated: 4/5/06

Respectfully submitted,

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